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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/376,794	08/18/1999	RAINER KROPKE	BEIERSDORF-5	6931
7590	03/05/2004		EXAMINER	
NORRIS MC LAUGHLIN & MARCUS P A 220 EAST 42ND STREET 30TH FLOOR NEW YORK, NY 10017			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/376,794	KROPKE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gollamudi S Kishore, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 December 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 18-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 18-26 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

### DETAILED ACTION

The amendment dated 12-15-03 is acknowledged.

Claims included in the prosecution are 18-26.

#### *Claim Rejections - 35 U.S.C. ' 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
2. Claims 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 771 566 or Magdassi or FR 2667 072 cited previously, in view of Jordan (5,885,617).

EP, Magdassi and FR disclose emulsion compositions containing chitosan and phospholipid (note the abstract, Tables and claims of EP; columns 5 and 8 and claims of Magdassi; note Examples on page 11 and the English translation of FR).

What is lacking in EP is the specific recognition that the lecithin present is known for its anti-tack property. EP does not explicitly state the molecular weight and the

degree of deacylation. Assuming they are different, the reference clearly teaches that these polysaccharides stabilize the emulsions and that chitosans with different molecular weights and degree of deacylation are readily available in the market (page 2).

Similarly Magdassi does not specifically teach that the phospholipids in the composition reduce the tackiness of the composition. Magdassi does not specifically teach the molecular weight and the degree of deacylation. As pointed out above, it is deemed obvious to one of ordinary skill in the art to use a specific chitosan in the teachings of Magdassi with the expectation of obtaining similar results. An artisan would be motivated to use any chitosan since EP shows that these are readily available in the market.

FR does not specifically teach that the phospholipids reduce the tackiness of the composition.

Jordan while disclosing pharmaceutical compositions teaches that lecithin is known to be an anti-tack agent (note col. 2, lines 51-58).

It would have been obvious to one of ordinary skill in the art that lecithin present in the compositions of EP, Magdassi or FR would reduce the tackiness of the compositions since Jordan teaches that lecithin is a known anti-tack agent. Based on the same reasoning one of ordinary skill in the art would expect lecithin to reduce the tackiness of composition irrespective of the compound contributing to the tackiness, in instant case, chitosan, its molecular weight and the degree of deacetylation.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the references have been improperly combined since Jordan is non-analogous art. This argument is not found to be persuasive for the following reasons. Instant specification clearly indicates that instant invention is directed to medicinal-pharmaceutical presentations and for medicinal use (see page 3, line 15 and page 12, line 31 for example). Jordan is directed to a pharmaceutical preparation; in essence both Jordan and instant preparation are in the same field of pharmaceutical and medicinal preparations and therefore, Jordan is not non-analogous art. Applicant argues that even if the references are combinable, the examiner, at best, has made out a *prima facie* case of obviousness. According to applicant, instant claims 24-26 claim a method of incorporating chitosan and a phospholipid into a preparation to reduce tackiness to skin while at the same time improving the stability of the preparation and instant specification on page 29 shows unexpected result of stability. This argument is not found to be persuasive since phospholipids are known emulsifiers. When two phases (oil and water) are combined without an emulsifier, the phases would separate and the purpose of adding an emulsifier is to prevent the phase separation; therefore, what applicant observes is an expected finding of a stable emulsion and not unexpected. The examiner cites the references of Cook (4,908,154; see examples), Voisin (4,411,813; see col. 2, lines 25-30 and Example 1) and JP 5,8201708 (abstract) in this context. For this reason, the added claims 24-26 are also included in this rejection.

3. Claims 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 771 566 or Magdassi or FR 2667 072 cited above, in view of either JP 63211208 or JP 03074316, further in view of Jordan cited above.

The teachings of EP, Magdassi and FR, which teach emulsions containing the phospholipids and chitosan, have been discussed above. It would have been obvious to one of ordinary skill in the art that the compositions of EP, Magdassi and FR are non-tacky since both JP references teach that the phospholipid containing cosmetic compositions are non-sticky (note the abstracts) and Jordan teaches that lecithin is a known anti-tack agent.

Applicant's arguments with regard to EP, Magdassi, FR and Jordan have been addressed above. The JP references each teach that phospholipid containing **cosmetic** compositions are non-sticky; applicant has not provided any specific arguments with regard to these references.

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*GSK*  
Gollamudi S Kishore, PhD  
Primary Examiner  
Art Unit 1615

GSK